MARYLAND HEALTH CARE COMMISSION

Analysis of Informal Public Comments and Staff Recommendations
State Health Plan for Facilities and Services:
Home Health Agency Services
COMAR 10.24.16

November 19, 2015

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I. Introduction

The current Chapter of the State Health Plan ("Plan"), COMAR 10.24.08, addresses nursing home, home health agency, and special hospital-chronic care services. This new Chapter (COMAR 10.24.16) will exclusively address home health agency (HHA) services.

COMAR 10.24.16 was developed by Commission staff with the assistance of a 2015 HHA Advisory Group that included representatives from Maryland HHAs of varying size, geographic location, and type, as nominated by the Maryland National Capital Homecare Association (MNCHA). Other participants on the Advisory Group included a Residential Services Agency (RSA) provider, a consumer, and State and federal regulatory agencies including the Office of Health Care Quality (OHCQ), Medicaid, and the Centers for Medicare and Medicaid Services (CMS). The HHA Advisory Group convened for three meetings during the months of February through April 2015.

To facilitate discussion at each of the meetings, Commission staff developed and distributed a *White Paper: A New Approach for Planning and Regulatory Oversight of Home Health Agency Services in Maryland*, which provides an overview of HHA services in Maryland, as well as background papers on various issues regarding HHA regulation in Maryland. Copies of the meeting agendas, *White Paper*, background papers, and summaries of meetings are posted on the Commission's website at
http://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hha.aspx

A new conceptual approach for planning and regulating HHA services in Maryland, as outlined in the *White Paper*, was presented by staff to the Commission at its February 2015 meeting. A follow-up presentation at the September 2015 Commission meeting highlighted the key provisions of the draft HHA Chapter, which was posted on the Commission's website September 30, 2015, seeking informal public comments through October 30, 2015. Comments were received from three organizations:

- Erickson Living (Adam Kane)
- Maryland National Capital Healthcare Association (MNCHA) (Ann Horton)
- Maxim Healthcare Services (Andy Friedell)

The remainder of this document provides a summary of comments received during the informal public comment period, and staff's analysis and recommendations. A complete set of the written comments received on the draft HHA Chapter is attached.

II. Summary and Staff Analysis of Informal Public Comments

Regulation .03 Issues and Polices: HHA Services

- Maxim Healthcare Services:

  CMS' Star- Rating System and "current methodology does not always reflect the quality of care being provided to certain populations – particularly those with progressive disease." "If the Commission determines to use the CMS Star-Rating scores as a measure of quality in the provision of HHA services under Medicare, we would suggest that it allow providers to also provide detailed written explanation of scores."

Staff Analysis and Recommendation:

Staff believes that using CMS' Star Rating scores provides an objective measure of quality that compares HHAs nationwide. Allowing descriptive explanations may be considered as a more subjective way for assessing an HHA's quality performance. In response to a related issue, **staff recommends** adding new language to Regulation .03, as follows:

> .03C. Home Health Agency Quality Measures and Performance
> . . .
> Qualifying factors for an application to be considered would depend on the type of applicant. Existing Medicare-certified HHAs in Maryland seeking to expand and applicants with experience in operating Medicare-certified HHAs in other states will need to demonstrate high quality performance on the CMS Star Rating system for HHAs and Home Health Compare measures. For those applicants with multiple Medicare-certified HHAs, seeking to either expand or establish an HHA in Maryland, the average performance score will be used.[8]
>
> New footnote:
> [8]An applicant's average performance score would be calculated based on the individual scores of all its Medicare-certified HHAs reporting on CMS' Home Health Compare and HHCAHPS.

Regulation .04 Need Determination for HHA Services

- Maxim Healthcare Services:

  "[T]o ensure all consumers are able to be comfortable in obtaining their full amount of prescribed services, it would be greatly preferable to allow a dually-eligible patient to be able to choose to receive all of their services from their chosen Medicare-certified provider, despite geographical restrictions within the state on a provider agency's ability to practice."

"The Commission may want to consider allowing consumers aging out of a [Medicaid] waiver program to retain their trusted caregivers, enhancing this care continuity, as long as their existing chosen provider is Medicare-certified in another jurisdiction."

Staff Analysis and Recommendation:

The Commission regulates the establishment of only one type of home care provider through its CON program, HHA services. Many of the concerns raised by Maxim Healthcare Services relate to coordination of services between licensed RSA and HHA providers, as well as serving dual-eligible clients. Care coordination and continuity of services may be challenging under existing licensure, Medicaid and Medicare regulations, but these issues are more properly addressed by OHCQ, Medicaid and CMS. **Staff recommends** no change be made to address this issue in Regulation .04.

- Maryland National Capital Homecare Association:

"We feel there is a threshold over which there can be no significant improvement in quality by adding more providers to a county or jurisdiction already flooded with providers… In some of Maryland's rural areas, we are concerned that the availability of clients and qualified clinical staff will be negatively impacted by the addition of new home health agencies providing traditional adult home care services through Medicare or Medicaid."

"We would like to work with the Commission to determine a threshold that will create a restriction based on the current number of active home health agencies in a jurisdiction for both adult and pediatric services. Thereby establishing a combination of an HHI of 0.25 and fewer than X active agencies."

Staff Analysis and Recommendation:

As provided in Regulation .04, a jurisdiction is identified as having a need for additional HHA services if the jurisdiction meets one of the following three criteria: (1) it has insufficient consumer choice of HHAs; (2) it has a highly concentrated HHA service market; or (3) it has an insufficient choice of HHAs with high quality performance. Insufficient consumer choice is considered to exist in a jurisdiction in which consumers have two or fewer Medicare-certified HHAs that served 10 or more clients each year during the most recent three-year period for which data is available.

The Herfindahl-Hirschman Index (HHI) is a widely accepted measure of market concentration proposed for use in this State Health Plan chapter. A jurisdiction having an HHI of 0.25[1] or greater is considered to have a highly concentrated HHA market.

[1] According to the Department of Justice and Federal Trade Commission *2010 Horizontal Merger Guidelines*, a market with HHI above 2500 is considered as "highly concentrated." For ease of interpretation, the HHI is divided by 10,000.

It is important to clarify that a competition index of .25 or higher does not imply that there is insufficient consumer choice. Rather, it means that a few HHAs serve a very large proportion of the total clients in the jurisdiction. Thus, by definition, the jurisdiction is not a competitive HHA market and research has indicated that quality improves in more competitive markets. Therefore, even if there is sufficient consumer choice, a jurisdiction with a highly concentrated market with a disproportional market share of clients served by a few agencies, may still be identified as having a need for additional HHA providers.

Staff believes that MNCHA's concern for potential negative impact of new HHA providers on existing HHAs' caseloads and clinical staffing resources is addressed by allowing gradual growth in the supply of HHAs, as described in Section .10 of the draft HHA Chapter. Staff agrees that rapid introduction of new competitors can strain the supply of labor, resulting in higher personnel costs or disruption in the ability to cover all the necessary nursing and therapeutic specialties all of the time. The Chapter provides for gradual growth in the number of HHAs. This will result in less impact on existing HHAs in a jurisdiction and also will provide new market entrants with a better chance for success. Rules intended to provide for gradual entry of new market entrants are described in .04 and .10 of the regulation.

Staff welcomes MNCHA's input on selection of quality measures and required performance threshold levels that must be achieved. **Staff recommends** no change be made to address this issue in Regulation .04.

- Erickson Living:

  "Strongly urge the Commission to retain the Specialty HHA designation."

  "We believe the Specialty HHA designation recognizes the significance of integrated care models with a medical home component… In the future, if Erickson Living opens a new CCRC in a jurisdiction where no need for HHA services is identified, the new CCRC will be unable to apply for a CON to provide home health services to its residents."

Staff Analysis and Recommendation:

The existing HHA Chapter recognizes two types of HHAs (general and specialty) and employs different policies for such agencies. The current Chapter requires CON approval to establish each type of HHA. A general home health agency is defined as "a home health agency that provides a full range of home health services that are not restricted as a specialty home health agency."

A specialty HHA is defined in the current Chapter as an HHA that provides:

(i) Services exclusively to a pediatric population;

(ii) An array of services exclusively to a population group limited by the nature of its diagnosis or medical condition;
(iii) To all population groups a highly limited set of services that can offer acceptable quality only through specialized training of staff and an adequate volume of experience to maintain specialized skills; or
(iv) Services exclusively to the residents of a specific continuing care retirement community (CCRC).

The specialty HHA designation is only recognized by the Commission for purposes of CON regulation, and any type of HHA authorized to operate in Maryland must meet the same licensure and certification requirements. This means that each type of HHA must directly, or through a contractual arrangement, provide skilled nursing and home health aide services, and at least one other home health care service that is centrally administered (as defined in statute) to a sick or disabled individual in the residence of that individual.

Neither OHCQ, which is responsible for licensing and certification of HHAs in Maryland, nor CMS recognizes the specialty HHA designation. Both general and specialty Commission-designated HHAs are licensed and certified simply as home health agencies. A general HHA may serve populations defined under the specialty HHA designation and, in fact, the Commission requires a CCRC-based HHA to provide residents with a full list of available HHAs in the jurisdiction.

The key distinction in current CON regulation of general and specialty HHAs is that a proposed general HHA has to adhere to a HHA need forecast based on a specified need projection methodology, while a proposed specialty HHA has the burden of proof to demonstrate need.

Because the new approach for determining need in a jurisdiction is based on consumer choice of quality HHA providers, Commission staff believes that it is not necessary to continue the specialty designation and recommends that all licensed HHAs in Maryland should be uniformly regulated through the Commission's CON program. Furthermore, CCRC residents are not precluded from obtaining services from any HHA authorized to serve the jurisdiction in which they live, even if their CCRC operates a specialty HHA. Staff believes that the choices available to CCRC residents are adequate and do not require the maintenance of a specialty designation in order for CCRC residents to have access to quality HHA services. Staff recommendations for changes in CON regulation are meant to assure that expansion and new market entry opportunities for HHAs are linked with measured performance on quality indicators.

A proposed new HHA or existing HHA seeking to expand can certainly seek to tailor its services to successfully serve a niche market demand. Staff believes that the fairest approach is to require that persons seeking to serve a specified population (e.g., the pediatric population or a CCRC

resident population) or provide a specialized set of services be required to meet the same qualifying factors as other HHA applicants.

Staff recommends that current specialty agencies be grandfathered, with authorizations to provide HHA services as indicated on the agency's HHA license. Therefore, Erickson Living's three separately licensed home health agencies (Charlestown Community HHA, Oak Crest Village Home Health, and Riderwood Home Health) would retain their authority to exclusively serve their own CCRC residents. In response to Erickson Living's comments, should an additional CCRC campus be opened by an existing CCRC in the same jurisdiction as one of its own existing CCRC-based HHAs, the newly established CCRC with common ownership could be served by the existing specialty HHA.

To address the comments, **staff recommends** that the following language be added to the draft HHA Chapter at Section .04, Need Determination for HHAs:

> .04B. A specialty home health agency awarded a CON by the Commission prior to the adoption of these regulations shall maintain its authority, provided that the specialty HHA retains Medicare certification and otherwise complies with State law and regulations.
>
> (1) No new specialty HHAs will be established. Any proposed establishment of an HHA shall address jurisdictional need as defined in Regulation .04.
>
> (2) An existing CCRC-based HHA exclusively serving its own CCRC residents may expand its authority within it existing authorized jurisdiction to exclusively serve the residents of another CCRC that has common ownership with the CCRC at which the existing specialty HHA is based.

.06 Certificate of Need Application Acceptance Rules: HHA Services
C. Qualifications for All Applicants

- Maryland National Capital Homecare Association:

"Item (2) indicates that the Commission will only accept a CON application submitted by an applicant that has not been convicted of Medicare or Medicaid fraud within the last 5 years. Our members feel strongly that this is not an adequate qualifier and respectfully request that this be increased to 10 years."

"Item (7) indicates that applicants must demonstrate a record of serving all applicable payer types, such as Medicare, Medicaid, private insurance, HMOs and self-pay patients. It is not clear how Maryland Residential Service Agencies providing home care services will be able

to demonstrate experience with Medicare as they would not have held a CON in order to provide these services, and we are seeking further clarification from the Commission on this point."

Staff Analysis and Recommendation:

CMS regulations (42 CFR Part 424.535) regarding conditions for revocation of enrollment in the Medicare program refer to 10 years as the timeframe for provider exclusion, providing as follows:

> *The provider, supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.*

For this reason, **staff recommends** changing the timeframe in draft COMAR 10.24.16.06C(2) from 5 to 10 years as follows:

> .06C Qualifications for All Applicants. The Commission will only accept a CON application submitted by an applicant that:
>
> ...
>
> (2) Has not been convicted of Medicare or Medicaid fraud or abuse within the last [five] <u>ten</u> years.

Similarly, **staff recommends** changing the timeframe in draft COMAR 10.24.16.11F(3) regarding acquisition of an HHA from five to ten years as follows:

> .11F. Information Required to Obtain a Determination of Coverage for an HHA Acquisition. The Commission requires the following information from the purchaser and seller of an HHA, in addition to information required under COMAR 10.24.01.03A:
>
> . . .
>
> (3) A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony within the last [five] <u>ten</u> years.

Staff recommends that no changes be made to COMAR 10.24.16.06C(7)[2] as the current language refers to those payer types that are *applicable* to the type of applicant. "Demonstrates a record of serving all *applicable* payer types, such as Medicare, Medicaid, private insurance, HMOs and self–pay patients; …." (*italics* added)

[2] Note: renumbering of the subparts under COMAR 10.24.16.06C has changed, so that (7) in the draft is now (8).

.06C. Qualifications for All Applicants. The Commission will only accept a CON application submitted by an applicant that:

. . .

(3) Has received at least satisfactory findings reflecting no adverse citations on the most recent two survey cycles from its respective state agency or accreditation organization, as applicable….

- Maxim Healthcare Services:

"Maxim urges the Commission to adopt more definite criteria for this element of qualification, such as maintaining accreditation through a state-recognized deeming authority, including Joint Commission, Accreditation Commission for Health Care, or Commission on Accreditation for Home Care. As such, providers will have clear guidance on whether they are in a position to apply for a CON."

Staff Analysis and Recommendation:

Staff recommends adding a new qualification at COMAR 10.24.16.06C(4) to provide:

(4) Has maintained accreditation through a state-recognized deeming authority, as applicable, for at least the three most recent years….

Staff recognizes that it is not necessary to list the specific accreditation organizations (AO) which currently have deeming authority, as such AOs may change.

Staff recommends changing .07D, Quality Measures for Licensed and Accredited Hospital, Nursing Home, or Maryland Residential Service Agency (RSA) Providing Skilled Nursing Services, to add parallel language in Subsection (1) to provide as follows:

(1) In the case of a Maryland licensed RSA applicant, it has operated with an established quality assurance program that includes systematic collection of process and outcome measures, and experience of care measures and has maintained accreditation [been accredited] through a deeming authority recognized by Maryland's Department of Health and Mental Hygiene for at least the three most recent years [by an accreditation organization recognized by DHMH as providing deemed status for Medicare and Medicaid certification].

.07 Establishment of HHA Quality Measures and Performance Levels for Applicants

B. Quality Measures for Maryland Medicare-certified HHAs. In order for an application from a Maryland Medicare-certified HHA to be accepted for a scheduled review cycle, it shall:

. . .

(3) Demonstrate that it has maintained or improved its level of performance ….

- Maryland National Capital Homecare Association:

"In effect, this could eliminate some of Maryland's most highly-qualified agencies from expanding into new territories. For example, if an agency moves from a perfect score to one point less than a perfect score (still in an excellent range), that agency will not meet this 'maintain or improve' standard. We suggest that the Commission strike this from the health plan and instead establish a range of qualifying quality indicators without the maintenance requirement."

"Also in this section, a great deal of concern was expressed by our membership about the ambiguity of the quality standards that will be used and the potential of repeated variations in the quality standards as various jurisdictions are opened. This one factor is our biggest concern – that this 'moving target' greatly inhibits an agency's ability to prepare or plan for future expansion with ever-changing qualification requirements. It is our hope that the Commission can establish best practices that can be standardized throughout the process in order to avoid an 'impossible to navigate' marketplace and we are happy to assist with development of those standards."

Staff Analysis and Recommendation:

Staff recommends moving the requirement that an applicant "[d]emonstrate that it has maintained or improved its level of performance on the selected process and outcome measures during the most recent three-year reporting period" for both Maryland and non-Maryland Medicare-certified HHAs from draft .07B(3) and .07C(3), respectively, and including it under COMAR 10.14.16.09 Certificate of Need Preference Rules in Comparative Reviews as new

> .09**B. Maintained or Improved Performance.** An HHA that demonstrates maintenance or improvement in its level of performance on the selected process and outcome measures during the most recent three-year reporting period will be given preference over an applicant that did not maintain or improve its performance."

Staff recognizes that CMS' quality measures are evolving, which is the primary reason Commission staff has developed a process for including public comment each time quality and

performance measures are published prior to establishing the CON review schedule. Potential applicants will be better informed to determine their eligibility to apply based on the most recent and available data. Commission staff welcomes MNCHA's input on the selection of quality measures and establishment of performance threshold levels. **Staff recommends** no change to address this issue in Regulation .07.

C. Quality Measures for Non-Maryland Medicare-Certified HHAs

- Maxim Healthcare Services:

  "Maxim urges the Commission to consider the fact that the CMS Star-Rating system does not take fully into account all types of patients, using several measures that are inappropriate to assess whether high quality home care services have been provided for certain types of patients, and failing to use other, more appropriate, measurements of quality processes and outcomes (see our comment in .03 above)."

Staff Analysis and Recommendation:

Staff believes that using CMS' Star Rating scores provides an objective measure of quality that compares HHAs nationwide. For providers with multiple Medicare-certified HHAs either in Maryland or another state, staff proposes to use the average of the individual HHA's CMS Star Rating scores. **Staff recommends** no change to Regulation .07C in response to this comment.

.08 Certificate of Need Review Standards for HHA Services

- Maryland National Capital Homecare Association:

  "[P]age 17, section .08 C Financial Accessibility indicates that applicants must only 'agree to become licensed to maintain Medicare and Medicaid certification' which appears to be an inconsistency in the chapter."

Staff Analysis and Recommendation:

Staff recommends clarifying the CON review standard on financial accessibility to read as follows:

> An applicant shall be or agree to become licensed [to maintain] and Medicare-and Medicaid-certified and agree to maintain Medicare and Medicaid certification and accept clients whose expected primary source of payment is either or both of these programs.

.10 Gradual Entry of New Market Entrants

- Maryland National Capital Homecare Association:

"We appreciate the recognition by the Commission that gradual entry of agencies is the right approach. The Commission categorizes agencies in Table 1 of the Annual Home Health Agency Survey, FY 2013 report as Parent Agencies Authorized to Serve, Parent Agencies Actually Serving at Least 1 Client, and Parent Agencies Actually Serving at Least 10 Clients. In this section, which of these three categories are referred to as 'existing HHAs'? This is important in determining how the current market situation is defined and how many agencies the Commission will be considering to add to the various jurisdictions."

Staff Analysis and Recommendation:

Staff recommends clarifying COMAR 10.24.16.10, Gradual Entry of New Market Entrants, to read as follows:

> In order to promote [allow] gradual [entry] growth in the number of HHAs in Maryland and avoid [without] excessive disruption or destabilization of the existing HHA staffing resources, the Commission will consider the number of existing parent HHAs actually serving at least 10 or more clients in a jurisdiction during the most recent three-year period for which data is available, and limit the number of new entrants authorized by CON approval for any given review cycle to ….

.11 Acquisition of a Home Health Agency

.11F (1) "A purchaser shall affirm that the services historically provided by the HHA being acquired will not change as a result of the proposed acquisition…"

- Maxim Healthcare Services:

"Maxim requests that the Commission consider that some changes in this area are positive, for instance, if an HHA proposing to be acquired is not fully serving its permitted geographic region or all patient types within its license and the intended purchaser plans to do so. We recommend that this section be amended to read, 'The purchaser shall disclose whether there will be any change to the services historically provided by the HHA being acquired as a result of the proposed acquisition…'"

Staff Analysis and Recommendation:

Staff recommends clarifying the intent of the language in COMAR 10.24.16.11F(1) to read as follows:

> A purchaser shall affirm that it will provide, at a minimum, the services historically provided by the HHA being acquired [will not change as a result of the proposed acquisition].
>
> **.11F(4) A purchaser shall disclose any record of Medicare or Medicaid fraud or abuse ….**

- Maxim Healthcare Services:

> "Maxim urges the Commission to adopt a more definitive standard, such as 'A purchaser shall disclose any record of a court or regulatory body's final determination of any Medicare or Medicaid fraud or abuse within the last five years…'"

Staff Analysis and Recommendation:
See staff's earlier analysis regarding .06C, "Qualifications for All Applicants" and 42 CFR citation. **Staff recommends** clarifying the language in .11F(4) as follows:

> A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony involving [shall disclose any record of] Medicare or Medicaid fraud or abuse within the last ten years.

For consistency purposes, staff recommends clarifying the language in .11F(3) as follows:

> A purchaser [shall disclose whether], any of its principals, a related entity, or a principal of a related entity shall not have [has ever] pled guilty to, been convicted of, or received a diversionary disposition for a felony within the last [five] ten years.

.11F(7) If the purchaser is an existing provider of Medicare-certified HHA services, whether in Maryland or another state, it shall disclose deficiencies cited by the applicable state agency or accreditation organization for the most recent two survey cycles and document completion of any required plan of correction . . . .

- Maxim Healthcare Services:

> "Maxim suggests that the Commission adopt a standard whereby providers disclose any involuntary terminations of either Medicare or Medicaid provider agreements occurring in the five (5) year period preceding the application to the Commission. This will alleviate the Commission having to review potentially burdensome amounts of information from larger providers and will make the process fair for large and small providers alike."

Staff Analysis and Recommendation:

Staff recommends clarifying the types of deficiencies to be disclosed and revise .11F (7) to read as follows:

> If the purchaser is an existing provider of Medicare-certified HHA services, whether in Maryland or another state, it shall disclose condition-level deficiencies cited by the applicable state agency or accreditation organization for the most recent two survey cycles and document completion of any required plan of correction . . . .

Staff recommends clarifying language be added to .11 F as follows:

> F. Information Required to Obtain [for] a Determination of Coverage for an HHA Acquisition.

.13 Definitions

Staff Recommendation:

Staff recommends that the following new definitions be added to the HHA Chapter when adopted as proposed permanent regulations:

(9) *Condition-level deficiency* means noncompliance with the conditions of participation or conditions of coverage where the deficiencies are of such character as to substantially limit the provider's capacity to furnish adequate care or which adversely affect the health and safety of patients (42 CFR §488.705 and §488.24).

(38) *Specialty Home Health Agency* means a home health agency awarded a Certificate of Need prior to January 1, 2016 that provides services which could not otherwise be provided by a general home health agency:

(a) Services exclusively to the pediatric population;

(b) An array of services exclusively to a population group limited by the nature of its diagnosis or medical condition;

(c) To all population groups a highly limited set of services that can offer acceptable quality only through specialized training of staff and an adequate volume of experience to maintain specialized skills; or

(d) Services exclusively to the residents of a specific continuing care retirement community.